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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,008	12/22/2000	Christian Viskov	03806.0488-00000	7790

22852 7590 06/25/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/742,008

Applicant(s)

VISKOV, CHRISTIAN

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-14, 22 and 23, drawn to a process for preparing a polyanion for use as an intermediate in the preparation of a cyclosporin derivative, comprising treating a cyclosporin with a hexamethyldisilazane metal salt; or a process for preparing a cyclosporin derivative substituted at 3-position, comprising preparing the polyanion, classified in class 514, subclass 9, and class 530, subclass 317.

II. Claims 15 and 16, drawn to a method for preventing or treating a retrovirus infection or an associated syndrome, comprising administering to a mammal a cyclosporin derivative defined in part 1), 2), 3), 4), or 7) of claims 14, classified in class 514, subclass 9, and class 530, subclass 317.

III. Claim 17, 19 and 20, drawn to a method for treating a chronic inflammatory disease, an autoimmune disease or inflammation, comprising administering to a mammal a cyclosporin derivative in part 5), or in part 6) or 8) of claims 14, classified in class 514, subclass 9, and class 530, subclass 317.

IV. Claim 18, drawn to a method for preventing or treating an autoimmune disease or preventing rejection of a transplant organ, comprising administering to a mammal a cyclosporin derivative in part 6) or 8) of claims 14, classified in class 514, subclass 9, and class 530, subclass 317.

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V. Claim 21, drawn to a method for treating schistosomiasis, filariasis, leishmaniasis, coccidioidomycosis or malaria, comprising administering to a mammal a cyclosporin derivative in part 6) or 8) of claims 14, classified in class 514, subclass 9, and class 530, subclass 317.

Should Group I, II, III, IV or V be elected, applicant is required to select one cyclosporin compound from claim 4 or claim 14 (or claim 23) with each R<sub>1</sub>, R<sub>2</sub>, R<sub>4</sub> to R<sub>11</sub>, and Z<sub>1</sub>, Z<sub>2</sub> and Z<sub>4</sub>-Z<sub>11</sub> defined. Each cyclosporin, absent factual data to the contrary, is a distinct peptide. This is not a species election.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-V are distinct from each other because the method steps, the material used and outcomes are wholly different among inventions, e.g., Invention I is to make a polyanion intermediate of cyclosporin or a cyclosporin derivative via polyanion intermediate, and Inventions II-V are directed to treat different diseases using various cyclosporin derivatives.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the recognized divergent subject matter, and because Inventions I-V require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the  
application. Any amendment of inventorship must be accompanied by a petition under 37 CFR  
1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Aaron Raphael on June 24, 2003 to request an oral election  
to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the  
examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The  
examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's  
supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers  
for the organization where this application or proceeding is assigned are (703) 308-0294 for  
regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding  
should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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June 25, 2003

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800